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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 17

Application Number: 09/829,707
Filing Date: April 10, 2001
Appellant(s): MORRISON, JAMES U.

W. Scott Harders
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/20/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 15-27 and 43 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,643,874	BREMER ET AL	7-1997
6,309,663	PATEL ET AL	10-2001
6,387,361	ROSNER	5-2002

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 15-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al (US Patent No. 6,309,663).

Appellant claims a chemical composition used to stimulate weight loss in a patient, consisting essentially of: acarbose; and a sustained release matrix, wherein said acarbose and sustained release matrix are combined to form a mixture. Additional limitations in the dependent claims include the acarbose being about 20% to about 40% by weight of said composition; the acarbose being present in an amount of about 25mg to about 300mg; the composition further consisting essentially of a filler, a glidant and a lubricant; specific types of glidant, lubricant, and sustained release matrix; the composition being covered with a coating; and specific type of coating.

The Patel et al patent discloses a pharmaceutical composition that comprises surfactants and a hydrophilic therapeutic agent (see abstract), whereby the hydrophilic therapeutic agent may be selected as acarbose (see column 31, lines 57 and 58). Patel et al discloses that the pharmaceutical compositions may be in dosage forms, whereby the dosage form can be designed for extended release, which can be affected by a coated matrix composition (see column 38, 2nd paragraph). See the 3rd paragraph of column 38 and the first paragraph of column 40 for examples of cellulose derivatives that can be used to form the coating composition that include ethyl cellulose, hydroxpropyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxymethyl cellulose, hydroxypropyl methyl cellulose phthalate, and hydroxypropyl methyl cellulose succinate. These cellulose derivatives encompass the subject matter of instant Claims

24-27. The Patel et al patent further discloses the presence of other additives in the pharmaceutical compositions that include fillers and lubricants (see column 36, 4th paragraph) as set forth in instant Claims 18 and 20. The Patel et al patent discloses that pharmaceutically acceptable bases such as magnesium aluminum silicate and synthetic aluminum silicate (see column 37, lines 2 and 3) may be added to the composition, which fall within the broadly recited colloidal silica that is set forth in instant Claims 19 and 21. See Table 18 in column 23 of the Patel et al patent wherein sodium lauryl sulfate and sodium stearyl fumarate may be included in the pharmaceutical composition of the Patel et al patent, which are also set forth in instant Claim 22. The Patel et al patent further discloses magnesium stearate as part of the pharmaceutical composition, which is disclosed in instant Claim 23. In column 54, line 26, Patel et al discloses that the amount of acarbose present in the composition thereof ranges from 50 to 100 mg, which is within the range of the amount of acarbose set forth in instant Claim 17 and also fall within the 20% to about 40% range of the composition set forth in instant Claim 16. The above described pharmaceutical composition of the Patel et al patent comprising acarbose and a coating anticipates the instantly claimed chemical composition comprising acarbose and a sustained release matrix.

Claims 15-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bremer et al (US Patent No. 5,643,874).

Appellant claims a chemical composition used to stimulate weight loss in a patient, consisting essentially of: acarbose; and a sustained release matrix, wherein said acarbose and sustained release matrix are combined to form a mixture. Additional limitations in the dependent claims include the acarbose being about 20% to about 40% by weight of said composition; the acarbose being present in an amount of about 25mg to about 300mg; the composition further consisting essentially of a filler, a glidant and a lubricant; specific types of glidant, lubricant, and sustained release matrix; the composition being covered with a coating; and specific type of coating.

The Bremer et al patent discloses glucosidase and/or amylase inhibitors that can be manufactured as pharmaceutical compositions for the combined use with a lipase

inhibitor in the treatment of obesity (see column 1, line 27 and column 2, lines 1-3). The Bremer et al patent discloses that the glucosidase and/or amylase inhibitor may be selected as acarbose (see column 2, lines 5-12). The Bremer et al patent discloses that the acarbose may be present in tablets that have controlled active substance release and increase residence time in the stomach (see Example D in column 6) which is within the meaning of the phrase "sustained release matrix" that is set forth in instant Claim 15. Example D discloses that the tablet comprises 50 mg of acarbose, which covers the amount of acarbose set forth in instant Claims 16 and 17. Example D sets forth the tablet as further comprising hydroxypropylmethycellulose, which is analogous to the hydroxypropylmethylcellulose that is disclosed in instant Claim 24; magnesium stearate, which is analogous to the metal stearates and magnesium stearate set forth in instant Claims 22 and 23; colloidal silicic acid, which is analogous to the colloidal silica set forth in instant Claim 21; and a hydroxypropylmethylcellulose that is part of the coating film, which is analogous to the subject matter of instant Claims 25 and 26. See column 5, 6th paragraph, wherein the Bremer et al patent discloses the compositions thereof as being useful for oral application with the usual pharmaceutical adjuvant material, for example, organic or inorganic inert carrier materials, such as water, gelatin, lactose, starch, talc, gums, polyalkyleneglycols and the like, and Bremer et al discloses that the pharmaceutical adjuvant materials include preservatives, stabilizers, wetting or emulsifying agents, salts to change the osmotic pressure or to act as buffers, which are analogous to the broadly claimed filler, glidant, and lubricant components that are set forth in instant Claims 19-20. The above describe pharmaceutical composition that can be used to treat obesity of the Bremer et al patent anticipates the instantly claimed chemical composition used to stimulate weight loss in a patient.

Claim 43 is rejected under 35 U.S.C. 102(a) as being anticipated by Rosner (US Patent No. 6,387,361).

Appellant claims a method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor.

The Rosner patent discloses a method of controlling weight in a human comprising administering to the human acarbose at meals with food containing carbohydrate, which anticipates the method of instant Claim 43.

(11) Response to Argument

Claim 43 stands rejected under 35 U.S.C. 102(a) as being anticipated by Rosner (US Patent No. 6,387,361).

Appellant's arguments filed in the Appeal Brief dated October 20, 2003 have been fully considered but they are not persuasive. Appellant argues that the Rosner patent is not a reference since the reference was not published before the filing date of the instant application. This argument is not persuasive since the invention of the Rosner patent was known or used by others in this country before the filing date of the instant application, as suggested by the filing date of the Rosner patent dated August 2, 1999.

Appellant further argues against the rejection on the ground that Rosner does not describe each and every element as set forth in Claim 43 because Rosner does not disclose administering a mixture of acarbose and a sustained release matrix. This argument is not persuasive since Claim 43 does not recite the presence of a sustained release matrix in the acarbose formulation, but does recite acarbose with food containing carbohydrate, which is within the scope of the acarbose formulation of the Rosner patent. Accordingly, the rejection of Claim 43 under 35 U.S.C. 102(a) as being anticipated by Rosner (US Patent No. 6,387,361) is maintained for the reasons of record.

Claims 15-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al (US Patent No. 6,309,663).

Appellant's arguments filed in the Appeal Brief dated October 20, 2003 have been fully considered but they are not persuasive. Appellant amended the claims by changing the term "comprising" to -- consisting essentially of --. Appellant argues that

by using the term "consisting essentially of" the claims now call for a composition of acarbose and a sustained release matix and any other component which does not alter the basic and novel characteristics of the composition. Appellant argues that the Patel patent discloses a composition which includes an "absorption-enhancing agent" alone with hydrophilic therapeutic agents, wherein the "absorption-enhancing agent" comprises at least two surfactants. Appellant argues that the composition of the Patel patent contains additonal components including at least two surfactants. Appellant argues that the instant claims exclude such additonal components because the introduction of at least two surfactants would "materially affect the basic and novel characteristics" of the claimed invention and therefore does not anticipate the instant claims (see Appellant arguments on pages 5-7 of the Appeal Brief filed October 20, 2003). This argument is not persuasive because each of the components set forth in the instantly claimed chemical composition are present as a component in the composition of the Patel et al patent, including components that are set forth in the instant claims and specification that may be selected as the "at least two surfactants" in the Patel et al patent. See column 35, line 37 of the Patel et al patent wherein "sodium lauryl sulfate" is listed as a surfactant, which is also recited in instant Claim 22 as a lubricant. See column 28, line 36 of the Patel et al patent wherein "stearic acid" may be selected as a hydrophobic surfactant, which is also disclose on page 8, line 5 of the instant specification as a possible component of the instantly claimed chemical composition. Since "sodium lauryl sulfate" and "stearic acid" are listed as surfactants for the pharmaceutical composition of the Patel et al patent as well as possible components for the instantly claimed compositions, the argument by Appellant that the surfactants listed in the Patel et al patent "materially affect the basic and novel characteristics" of the instantly claimed chemical composition cannot be held as an accurate statement. Furthermore, Appellant arguments cannot be considered valid since Appellant failed to set forth in the argument what is considered the "basic and novel characteristics" of the instantly claimed invention.

Appellant further argues that the appearance of the term "sustained release" in the Patel patent does not anticipate the sustained release matrix" as recited in the

instant claims. This argument is not persuasive because Appellant has not set forth any limitations in the claims drawn to the "sustained release matrix" except for indicating in instant Claim 24 that the sustained release matrix is hydroxypropylmethylcellulose. As indicated in the rejection, hydroxypropylmethylcellulose is set forth in the Patel et al patent.

Appellant further presents arguments with regard to features upon which Appellant relies which are not recited in the rejected claims. The Examiner maintains that the features upon which applicant relies (i.e., location of the release of the agent, pH-independence, the acarbose and sustained release matrix being dry mixed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the rejection of Claims 15-27 under 35 U.S.C. 102(e) as being anticipated by the Patel et al patent is maintained for the reasons of record.

Claims 15-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bremer et al (US Patent No. 5,643,874).

Appellant's arguments filed in the Appeal Brief dated October 20, 2003 have been fully considered but they are not persuasive. Appellant argues on page 10 and 11 of the Appeal Brief filed October 20, 2003 against the rejection of Claims 15-27 over the Bremer et al patent on the grounds that the claims as amended (changing "comprising" to "consisting essentially of") excludes the presence of other ingredients that would change the novel and basic characteristics of the claimed composition. If Appellant are referring to the novel and basic characteristics of the claimed composition as the acarbose and sustained release matrix, then this argument is not persuasive since there is no indication in the Bremer et al patent that the presence of the lipase inhibitor in the composition of the Bremer et al patent alters the chemical formula of the acarbose and the hydroxypropylmethylcellulose of the Bremer et al patent.

In the last paragraph on page 11 of the Appeal Brief, Appellant indicates that the claimed composition lacks a lipase inhibitor by using the language "consisting

essentially of". However, there is no indication in instant Claims 15-27 that a lipase inhibitor is not present in the composition since Appellant has not clearly defined "the basic and novel characteristics of the instantly claimed composition" in such a way that a lipase inhibitor would be excluded from the instantly claimed composition.

Appellant further argues that the appearance of the term "sustained release" in the Bremer et al patent does not anticipate the sustained release matrix" as recited in the instant claims. This argument is not persuasive because Appellant has not set forth any limitations in the claims drawn to the "sustained release matrix" except for indicating in instant Claim 24 that the sustained release matrix is hydroxypropylmethyl-cellulose. However, as indicated in the rejection, hydroxypropylmethylcellulose is set forth in the Bremer et al patent (see Example D).

Appellant argues that Bremer et al teaches away from administering a composition of acarbose and no other active ingredient for stimulating weight loss. Appellant argues that based on Bremer et al's disclosure, one of ordinary skill in the art would not expect that administering a composition consisting essentially of acarbose and a sustained release matix woud stimulate weight loss. This argument is not persuasive since the term "consisting essentially" is open to unlisted ingredients and the artisan would not gleam from the instantly claimed language that a "lipase inhibitor" is excluded from the instantly claimed composition since the utility of the composition disclosed in the Bremer et al patent also involves stimulating weight loss. Accordingly, the rejection of Claims 15-27 under 35 U.S.C. 102(b) as being anticipated by the Bremer et al patent is maintained for the reasons of record.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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November 19, 2003

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